

Message

From: Guyton, Kathryn [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=872D285E7848492CBE9AB0325C0FBADF-GUYTON, KATHRYN]
Sent: 1/23/2013 3:12:55 AM
To: Chiu, Wuehsueh [Chiu.Weihshueh@epa.gov]
Subject: Fw: Re: Follow up items from 11/26/12 OAR/NCEA-HHRA meeting

FYI ...

-----Forwarded by Kate Guyton/DC/USEPA/US on 01/22/2013 10:12PM -----

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To: Elizabeth Corona/DC/USEPA/US@EPA
From: Carl Mazza/DC/USEPA/US@EPA
Date: 01/22/2013 07:03PM
Cc: Annette Gatchett/CI/USEPA/US@EPA, Bryan Hubbell/RTP/USEPA/US@EPA, David Bussard/DC/USEPA/US@EPA, Debra Walsh/RTP/USEPA/US@EPA, Deirdre Murphy/RTP/USEPA/US@EPA, Ila Cote/RTP/USEPA/US@EPA, Jeff Frithsen/DC/USEPA/US@EPA, Jeneva Craig/DC/USEPA/US@EPA, John Vandenberg/RTP/USEPA/US@EPA, Kate Guyton/DC/USEPA/US@EPA, Kathleen Deener/DC/USEPA/US@EPA, Kathryn Sargeant/AA/USEPA/US@EPA, Kelly Rimer/RTP/USEPA/US@EPA, Kenneth Olden/DC/USEPA/US@EPA, Laura Kolb/DC/USEPA/US@EPA, Lydia Wegman/RTP/USEPA/US@EPA, Lynn Flowers/DC/USEPA/US@EPA, Marion Hoyer/AA/USEPA/US@EPA, Michael Stewart/RTP/USEPA/US@EPA, Steve Page/RTP/USEPA/US@EPA, Vincent Cogliano/DC/USEPA/US@EPA
Subject: Re: Follow up items from 11/26/12 OAR/NCEA-HHRA meeting
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Elizabeth...the attached (somewhat dated) Inside EPA article reports that Ken Olden told a recent meeting of the NAS BEST Committee that he plans to reduce the number of IRIS assessments underway from 50-60 to 20 assessments.

I understand (secondhand) that new schedules will be announced on the IRIS website and available in IRISTrack (<http://cfpub.epa.gov/ncea/iristrac/>) in the near future (beginning at the end of January.)

Can you let us know what the impact would be on chemicals of interest to OAR.

Thanks

December 7, 2012

Inside EPA

EPA Seeks To Curtail Ongoing IRIS Assessments To Increase Output
Update Appended

Managers of EPA's influential Integrated Risk Information System (IRIS) chemical hazard assessment program are proposing to prioritize and reduce the number of ongoing assessments that staff is handling by more than half in order to increase the program's efficiency and output and meet the 23-month goal for completing the studies set by Administrator Lisa Jackson.

Ken Olden, the new director of EPA's National Center for Environmental Assessment, which oversees the program, told members of the National Academies' Board on Environmental Studies & Toxicology (BEST) Dec. 6 that he intends to reduce the number of assessments underway from the existing 50 to 60 assessments to closer to 20.

"We've got between 50 and 60 assessments underway . . . We should be working on about 20 . . . 50 to 60 is just too many," he told BEST.

Olden's goal is a retreat from past agency efforts. The Government Accountability Office said in a report issued last January that EPA managers hoped to issue 40 assessments per year.

The NCEA director said that he sees prioritizing the assessments and reducing the number underway as important to reducing the amount of time it takes agency staff to complete an assessment. Olden explained that he and IRIS management will be speaking with the directors of the EPA programs that requested each assessment to "ask them if they really need" a particular assessment right now, he said.

He said he hopes that after speaking with IRIS' clients, he and IRIS managers can prioritize the chemicals and reduce the number of assessments under way.

EPA programs and offices nominate chemicals to the IRIS program for assessment, with the goal of having the best human health hazard information about an environmental contaminant they anticipate needing to make a decision or draft a rule upon in the future.

There are currently 63 substances slated for assessment, according to EPA's IRIS Track website. Last May, the agency proposed adding an additional 15 new substances to its list of pending assessments, including siloxanes, mercury, manganese, and others.

At that time, EPA listed 52 assessments already underway at the request of program and regional offices, though the agency said it was deferring decisions on several high-profile assessments -- including those for the plastic additive bisphenol-A and lead -- until after other federal programs assess them. The agency also delayed its pending ethanol assessment due to the complexity of the data.

But because the assessments have often taken IRIS so long to produce, some chemicals have fallen from the agency's agenda.

In recent years, IRIS chemical managers have on at least one occasion been unable to determine which program office requested an IRIS assessment, or why. In the case of another assessment, the IRIS review became less of a priority because industry greatly reduced the chemical's production. IRIS assessments are important in part because they often form the basis for agency rules and other decisions. They are also referenced and relied upon by state and local agencies around the world. But the lengthy delays of some controversial IRIS assessments, such as arsenic, dioxin and formaldehyde, have spanned decades. Many stakeholders, within the agency as well EPA advisors, environmentalists and public health activists, have long pressed IRIS staff to hasten their process. In 2009, the Government Accountability Office (GAO) listed the IRIS program among its high-risk government programs because it concluded that the process was so lengthy that assessments are obsolete upon publication.

Shortly after arriving at EPA, Jackson unveiled a new process for developing the assessments, with a goal of completing each within 23 months.

But as EPA has worked to speed assessments, it has drawn concerns from Congress industry groups that the agency is rushing to judgment and is not carefully considering uncertain science. They succeeded in forcing EPA to proceed with a programmatic and scientific review by the National Research Council that is not expected to be completed before spring 2014.

Pending IRIS Assessments

So far, no IRIS assessment has been completed in the 23-month timetable set by Jackson. But Olden, who took the helm in July, is vowing that it will happen under his watch.

"We are going to produce at least some assessments within 23 months. I think most of the things [necessary] to do this are within our control," he told the BEST board members, citing as an example the need to "align our staff."

Olden noted that he has other goals for improving the IRIS program, including several that he has proposed over the past few months, including making the program transparent, and its assessments consistent. He is also planning to have public workshops at the start of each assessment to discuss issues relevant to that chemical, a plan that industry has welcomed.

The agency is moving towards its first such public meeting, to discuss the long-ongoing assessment of inorganic arsenic (iAs). A Jan. 8-9 public workshop to discuss that assessment and relevant issues has been scheduled in Research Triangle Park, NC, according to Dec. 6 Federal Register notice.

The workshop "is designed to inform the planning for EPA's toxicological review of chronic exposure to iAs (cancer and noncancer effects) . . ." according to the notice. "Workshop participants will be asked to highlight significant new and emerging research, discuss methods for evaluating literature, identify critical research issues (including mode of action) that may impact the toxicological review, and discuss approaches for dose-response."

Olden has also sought public comments on how to improve the program, and he noted that one topic he has received many comments upon the peer review process for the assessments. In response, he noted that EPA's Science Advisory Board (SAB) is putting together a standing subcommittee tasked with reviewing IRIS assessments. And he said he aims to "ensure contractor peer reviews are done a lot more like [SAB reviews]."

In the past, these types of have reviews have sometimes been questioned because they do not have institutional knowledge about the IRIS program like a standing panel would, and the contractor panels are generally less rigorous. "I hope to produce a lot more [assessments] than [the SAB standing panel] can review," Olden told the BEST members. "They say they can do about six per year." We'd like to release "12 to 20" per year.

Industry's IRIS Priorities

Meanwhile, the chemical industry is also outlining its priorities for changes to IRIS. In a recent letter to Olden, the American Chemistry Council (ACC) reiterated its calls for a weight of evidence system for evaluating scientific studies and an ombudsman to oversee agency responses to peer reviews.

The group's Nov. 30 letter follows a public meeting at EPA last month, where Olden outlined some ideas for advancing and improving the IRIS. Olden also sought public suggestions on ways to improve the oft-maligned IRIS program.

Olden's appointment last summer has garnered optimistic reviews from long-time IRIS critics, including industry and other agencies, who appreciate Olden's open approach. Olden met with a number of industry groups and representatives of federal agencies in the fall. But some have also warned that while they find the change in attitude in IRIS' top ranks refreshing, they are waiting to see Olden's promised changes take effect.

"We are encouraged, but there remain many important issues to be addressed and there is a long way to go to implement the permanent changes needed to modernize IRIS," writes David Fischer, senior director of ACC's Chemical Products and Technology Division.

"ACC strongly believes that it is necessary for IRIS to foster early stakeholder engagement, apply systematic approaches to data evaluation, and adopt a consistent weight of evidence framework using the best available science to integrate study results to establish mode of action and cause and effect," Fischer writes. "This must be coupled with meaningful public comment and objective peer review processes, which include an 'honest broker' to ensure that scientifically-justified responses and revisions are made to fully address stakeholder and peer review comments."

ACC's wish-list is not new; the industry group has been pushing EPA for years to adopt a weight of evidence framework for use in its IRIS assessments, an issue bolstered by BEST's review of EPA's draft IRIS assessment of formaldehyde. The report included an additional chapter critical of the IRIS program generally, particularly with how it reached its conclusions and explained them.

Fischer's letter again cites the report's conclusions. "It's been nearly 20 months since the [National Research Council] made its well documented recommendations to the EPA on ways to improve IRIS, but the IRIS program has yet to establish a transparent plan (and time line) to implement many of the most critical improvements."

-- Maria Hegstad (mhegstad@iwppnews.com)

Editor's Note: This story has been updated to reflect the status of the IRIS assessment pipeline.

Carl Mazza
Science Advisor
Office of Air and Radiation, EPA
202-564-7427 (202-501-0600 fax)
Mazza.Car1@EPA.GOV

-----Elizabeth Corona/DC/USEPA/US wrote: -----

To: Annette Gatchett/CI/USEPA/US@EPA, Bryan Hubbell/RTP/USEPA/US@EPA, Carl Mazza/DC/USEPA/US@EPA, David Bussard/DC/USEPA/US@EPA, Debra Walsh/RTP/USEPA/US@EPA, Deirdre Murphy/RTP/USEPA/US@EPA, Ila Cote/RTP/USEPA/US@EPA, Jeff Frithsen/DC/USEPA/US@EPA, John Vandenberg/RTP/USEPA/US@EPA, Kate Guyton/DC/USEPA/US@EPA, Kathleen Deener/DC/USEPA/US@EPA, Kathryn Sargeant/AA/USEPA/US@EPA, Kelly Rimer/RTP/USEPA/US@EPA, Kenneth Olden/DC/USEPA/US@EPA, Laura Kolb/DC/USEPA/US@EPA, Lydia Wegman/RTP/USEPA/US@EPA, Lynn Flowers/DC/USEPA/US@EPA, Marion Hoyer/AA/USEPA/US@EPA, Michael Stewart/RTP/USEPA/US@EPA, Vincent Cogliano/DC/USEPA/US@EPA
From: Elizabeth Corona/DC/USEPA/US
Date: 11/27/2012 10:26AM
Cc: Jeneva Craig/DC/USEPA/US@EPA, Steve Page/RTP/USEPA/US@EPA
Subject: Follow up items from 11/26/12 OAR/NCEA-HHRA meeting

Hello Everyone,

Here are a few quick follow up items from our meeting on Monday, 11/26.

(1) The presentations from our November 13 IRIS stakeholder meeting are posted online:
http://www.epa.gov/iris/publicmtg_speakers.htm
(2) Here is the NAS website about the Dec. 13 meeting:
<http://www8.nationalacademies.org/cp/meetingview.aspx?MeetingID=6386&MeetingNo=2>

I will send you information on our PPRTVS and process by the end of this week, and information on the mouse-lung tumor workshop and IRIS schedule as soon as it become available.

If you have any questions, please do not hesitate to ask.

Warmest regards,
Elizabeth

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Elizabeth Corona, Ph.D.
Office of Research and Development
National Center for Environmental Assessment (8601P)
Phone: 703-347-0214
Fax: 703-347-8699